






TROCLEAN™ TROCAR CLEANING DEVICE

	DO NOT REUSE
	STERILIZED WITH ETHYLENE OXIDE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.



IMPORTANT INFORMATION

Please read all instructions, warnings and precautions before use. Correct application is essential for proper functioning of the product. Use only on the person it was provided to by a healthcare professional and only for the use it was intended.

INTENDED USE

The DeRoyal® TroClean™ Trocar Cleaning Device is a single patient use, sterile application and is used to clean the inside barrel of an endoscopic/laparoscopic trocar before and during the procedure.

WARNINGS

- Federal (U.S.A) law restricts this device to sale, distribution, and use by or on the order of a physician.
- This product is EO sterilized and for single patient use only. Please do not re-use or re-process to avoid irreversible injury and device malfunction.
- Do not use the product if the package is opened or damaged.
- Store this device in a dry, clean and safe place. Keep the device away from flammable and combustible chemicals and materials.
- Please follow universal guidelines upon medical waste disposal to avoid any potential cross-infection, environmental contamination or injury.
- Do not continue to use the product if there is any damage to the handle or foam while in use.
- The handle is malleable and is intended to flex while in use. However, product should be discarded if there is damage to the product while in use.
- X-ray detectable element is only housed in the handle of the TroClean™ device.
- Take proper care when using the product

to avoid damage to the swab during use. Ensure the device does not get caught on the valve or trocar edge.

INSTRUCTIONS FOR USE

1. The TroClean™ device offers a small and a large bore cleaning sponge with two different sticks. The small sponge is for 5-8 mm trocars and the large is for trocars 10-12 mm. Use the proper size sponge with the correct trocar size for ease of use.
2. The TroClean™ device is designed to firmly go into the cannula of the trocar while offering a malleable handle for ergonomics and flexibility when cleaning. The TroClean™ device handle is x-ray detectable, but do not deliberately drop device into the patient.
3. If the trocar system is spring loaded make sure to open the valve for ease of insertion and retraction of the TroClean™ device. Be aware of any sharp edges when using TroClean™ device and only insert TroClean™ device to the end of the barrel of the cannula.
4. Discard of the TroClean™ device post-surgery and follow universal guidelines upon medical waste disposal to avoid any potential cross-infection, environmental contamination or injury.

STORAGE AND TRANSPORT CONDITIONS

	KEEP DRY
	KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.



WARRANTY

DeRoyal® products are warranted for ninety (90) days from the date of shipment from deroyal as to product quality and workmanship. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**



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